

# CUSA EXcel<sup>®</sup>+

Ultrasonic Aspirator tender package

Limits uncertainty with  
Selectivity and Power



INTEGRA<sup>™</sup>  
LIMIT UNCERTAINTY

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## 1. Integra, the company

Integra develops, manufactures and markets implants and surgical instruments used in neurosurgery, reconstructive surgery, orthopaedic and general surgery.

Integra was founded in 1989, as the result of innovation which represent a technological breakthrough for the treatment of major burns. The company developed the first artificial dermal regeneration matrix composed of collagen.

From this initial technological achievement, Integra went on to develop the first dural regeneration matrix (with a principle of covering the neurocranium), a pioneering step into the domain of neurosurgery which established Integra as one of the key players in this field.

In 2005, Integra sought controlled growth and chose to diversify its activities by entering the orthopaedic surgery market.

In 2007, the group created its Europe – Middle East – Africa division based in Lyon, France.

**450** Is the number of Integra Lifesciences employees in Europe of an approximate total of 3000 employees in the Group as a whole (as at December 2009).

**7** Is the number of R&D centres and production sites in Europe (2009).

**30** Is the number of surgery courses organised by Integra in Europe to promote learning and knowledge sharing between surgeons (2009).

## 2. CUSA EXcel®+ ultrasonic aspirators applications

The ultrasonic aspirator CUSA EXcel®+ is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of tissue is desirable.

These procedures include the following areas:

- Neurosurgery,
- Gastrointestinal and affiliated organ surgery,
- Urological surgery,
- Plastic and reconstructive surgery,
- General surgery,
- Orthopaedic surgery,
- Gynecological surgery,
- Thoracic surgery,
- Laparoscopic surgery,
- Thoracoscopic surgery.

The CUSA EXcel® system can also be combined with electro surgery using the optional CUSA® Electrosurgical Module (CEM).



## 3. CUSA EXcel®+ ultrasonic aspirators technology

### Principle of Operation

The CUSA EXcel®+ Ultrasonic aspirator provides selective tissue fragmentation with simultaneous irrigation and aspiration. The system is comprised of the console and reusable handpieces. Each procedure also requires the use of a disposable or reusable tip and tubing set.

### Magnetostrictive Technology

The CUSA EXcel®+ console provides alternating current at 23 or 36 thousand cycles per second (kHz) to the handpiece (the frequency depends on which handpiece is connected to the console). In the handpiece, the current passes through a coil, which induces a magnetic field. The magnetic field excites a transducer of nickel alloy laminations, resulting in an oscillating motion in the transducer laminated structure – vibration – along its long axis.

### Cavitation

When the tip contacts tissue, the cells are fragmented as a result of both the ultrasonic pressure waves generated by the impact and by the resulting acoustic cavitation. Cavitation is the formation, growth, and implosion of vapor bubbles in the cellular liquid and is caused by the sound waves passing through the tissue. When these microbubbles implode, they generate a high-energy pressure wave that further fragments the tissue, enhancing the cellular disruption caused by the acoustic and mechanical forces generated by the vibrating tip.

### Irrigation

Sterile irrigation fluid flows from an Intravenous (I.V.) set (bottle or bag and I.V. administration tubing) to a variable speed peristaltic pump:

- The pump moves fluid at 1 to 10 cc/min; default flow is 3 cc/min. Adjustment buttons (blue up/down arrows on black buttons at the bottom of the irrigation display column on the control panel) enable the user to increase or decrease the irrigation flow.
- The pump can also accelerate to a Fast Flush speed, pumping at at more than 25cc/min. The Fast Flush pedal on the CUSA EXcel®+ system footswitch activates the Fast Flush feature. The pump pushes the fluid through the manifold irrigation tubing to a flue, a sleeve surrounding the vibrating tip. As the irrigation fluid passes through the flue, it cools the tip. When the fluid reaches the distal end of the tip, as much as 99% of it passes through two pre-aspiration holes in the tip, eliminating fluid pooling on the sterile field and continually clearing the suction system. The fluid that does not pass through the pre-aspiration holes irrigates the surgical site and suspends fragmented tissue.

### Aspiration

A vacuum pump in the console body provides up to 660 mm of mercury maximum vacuum at sea level. Adjustment buttons (green up/down arrows on black buttons at the bottom of the aspiration display column on the control panel) enable the user to increase or decrease the suction from 10 to 100% in 10% increments. The suction, which produces an air stream moving toward the vacuum pump, pulls irrigation fluid, fragmented tissue, and other materials through the distal end of the surgical tip. From the tip, the aspirated materials pass through the manifold suction tubing into the suction canister. From the suction canister, the air stream continues to flow through a contamination guard that filters any remaining particulate matter or moisture, preventing them from entering the vacuum pump. A suction pinch valve on the front of the console opens when the system is on and closes to stop suction in the following cases: In Run Status, when the Vibration pedal is released. In this case, the pinch valve closes for about one second, then re-opens to avoid any traction of tissue when removing the tip from the surgical area.

- When priming the irrigation system.
- When pressing the Fast Flush pedal.
- In Run Status, when the Vibration pedal is released. In this case, the pinch valve closes for about one second, then re-opens.
- In Lap Mode, when the Vibration pedal is released. This suction stoppage prevents depletion of the pneumoperitoneum. When the System Power switch is off, the suction pump remains off and the suction pinch valve remains closed. A button on the front of the suction pinch valve enables the user to open the valve manually.

### Cooling

The ultrasonic vibration generates heat. To reduce the heat, the CUSA EXcel®+ system includes a closed, recirculating cooling water system. This system pumps water from a cooling water reservoir, through a tube in the handpiece cable, through the handpiece, and through a return tube in the handpiece cable to the cooling water reservoir. Cooling water flows at 35 to 50 cc/min. As it passes through the handpiece, the water removes heat. Normal handpiece temperature, in sustained heavy use, remains at about 40° C. Use distilled water for the cooling water system because it does not contain natural minerals, chemical additives, or organic materials that are present in tap water. Any of these impurities in tap water can cause problems within the cooling water system.

### Tissue Selectivity (fig.1)

Tips used with the ultrasonic aspirator CUSA EXcel®+ surgeons selectively remove fluid-containing cellular material while fibrous and elastic tissues such as nerves and blood vessels are relatively unaffected at the ultrasonic frequencies used. Other tips are designed to selectively fragment bone and other hard tissues or to aggressively and relatively unselectively remove a wide variety of soft tissues.

Tissue strength affects both the fragmentation rate and the ability of any ultrasonic aspirator handpiece to remove tissue : Tissues with weak intracellular bonds are the easiest to fragment, and include tissues with moderate or high fluid content, such as certain neuro tumors (Meningioma), liver tissues, parenchyma, fat, and certain organs. Tissues with strong intracellular bonds are the most difficult to fragment, and include vessel walls, ducts, nerves, tendons, ligaments, and organ capsules. These structures contain less fluid and more collagen and/or elastin which provide resistance to fragmentation.

### Power Affects Tip Amplitude (fig.2)

The rate of fragmentation depends upon the Power setting, which determines the distance of tip stroke. As power increases, so does the tip stroke or amplitude, which results in a greater impact force and a higher tissue fragmentation rate. Conversely, a lower power produces a shorter stroke, less impact force, and a slower fragmentation rate. This is similar to striking a nail with a hammer. Short strokes are used to tap on the nail when precise placement is the goal while long strokes requiring more power are used to drive the nail.

The total amount of power available is directly impacted by the amount of reserve power available to the vibrating tip. Reserve power is necessary to maintain tip vibration when in contact with tissue (i.e., when the tip is under load). Like cruise control in a car going up a hill, more power is provided to maintain the speed of the car. Similarly, a feedback system in the CUSA EXcel® ultrasonic aspirator senses increased pressure when the tip is in contact with tissue and provides more power to maintain tip vibration.

Fig. 1

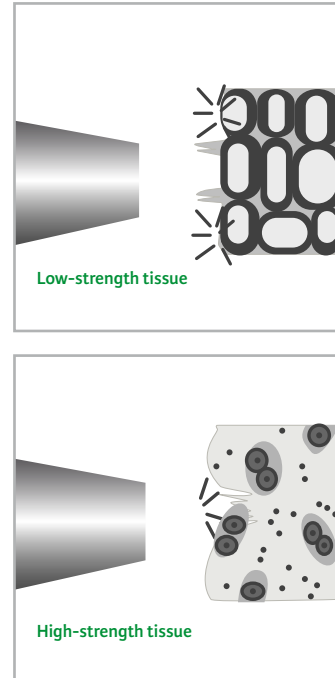
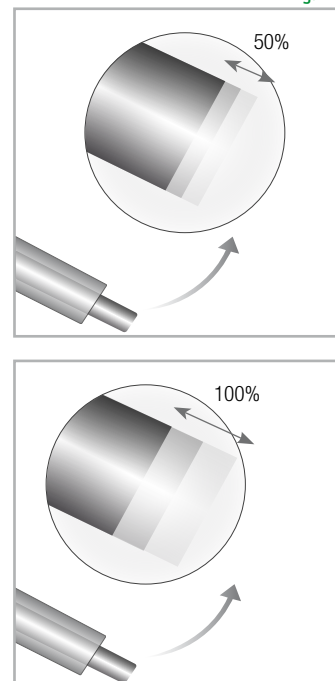


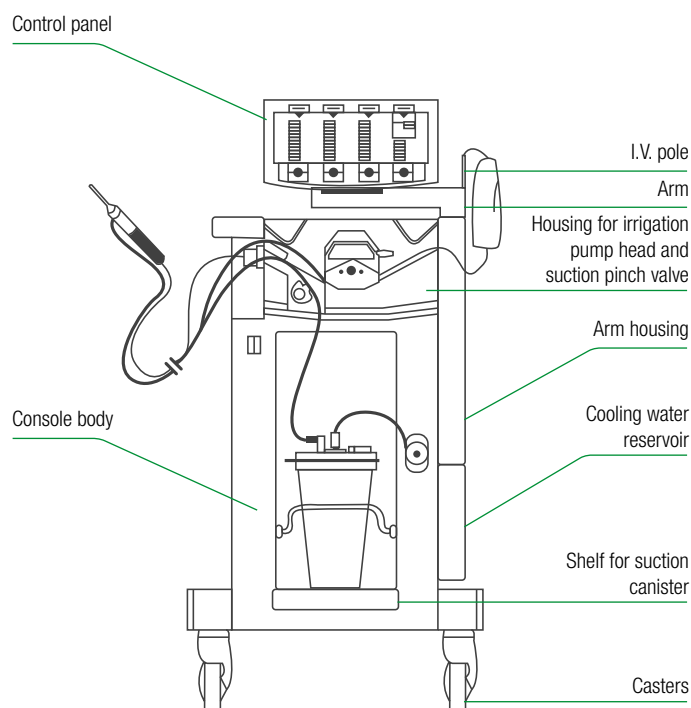
Fig. 2



## 4. CUSA EXcel®+ ultrasonic aspirator system

### Console

The CUSA EXcel®+ console is composed by a orientable control panel for an easy access, a powerful built-in pump, a decontamination filter to protect the system, a IV solution holder and 4 casters making the system easily moveable. The footswitch has two pedals in a base, and allows the user to activate two functions (ultrasonic vibration and fast flush).



### Control Panel

- Aspiration from 10 to 100%.
- Irrigation from 1 to 10 cc/min.
- Amplitude from 10 to 100%.
- Laparoscopic Mode: The system provides no suction to the handpiece until the vibration pedal is activated.
- Prime: Automatically increases irrigation rate to 30 cc/ min to pump irrigation fluid to the tip.
- Test: Verifies the handpiece is working properly by increasing tip amplitude to 100% and then decreasing it to 0%.
- TissueSelect™ Exclusive feature for an increased selectivity.



## 5. CUSA EXcel®+ handpieces

All CUSA EXcel®+ handpieces are driven by magnetostrictive technology and employs a unique closed, recirculating water cooling system to avoid any heat feeling for the surgeon.

### COMPACT Handpiece for Neuro and General Surgery (Fig. 1)

- 36 kHz Handpieces,
- Length 13.9 cm (5.48 in),
- Diameter 16.4 mm (0.65 in),
- Weight 68 g (2.4 oz),
- Maximum Amplitude 210  $\mu\text{m}$ .



### POWER Handpiece for Neuro and General Surgery

#### Straight (Fig. 2a)

- 23 kHz Handpieces (straight),
- Length 22.2 cm (8.75 in),
- Diameter 20.8 mm (0.82 in),
- Weight 180 g (6.4 oz),
- Maximum Amplitude 355  $\mu\text{m}$ .



#### Angled (Fig. 2b)

- 23 kHz Handpieces (angled),
- Length 22.5 cm (8.85 in),
- Diameter 20.8 mm (0.82 in),
- Weight 180 g (6.3 oz),
- Maximum Amplitude 185  $\mu\text{m}$ .



## 6. CUSA EXcel®+ tips

### 6.1. Tips for 23kHz handpiece

- MicroTip™ (1.57mm ID) Small ID for small tumors. (Fig. 1)



Fig. 1

- Standard Tip Series (1.98mm ID) Larger diameter for rapid tumor debulking. (Fig. 2a)



Fig. 2a



- Laparoscopic Tip (1.98 mm ID) Extended Life Tip (ELT\*) for Laparoscopic procedures. (Fig. 2b)



Fig. 2b

- MacroTip™ (2.64mm ID) Largest diameter tip. (Fig. 2c)



Fig. 2c

\* ELT (Extended Life Time): Tip is 6 times reusable



## 6.2.Tips for 36 kHz Handpiece

- PrecisionTip™ Series (1.14mm ID) Smallest diameter for access in restricted areas. (Fig. 1)

Fig. 1



- MicroTip™ Series (1.57mm ID) Better access for delicate procedures. (Fig. 2)

Fig. 2



Fig. 3

- Standard Tip Series (1.98mm ID) Larger diameter for rapid tumor debulking. (Fig. 3)



## 6.3. Specialty tips for 36 kHz Handpiece

### CUSA ShearTip™

- Designed for fibrous and tough tumors,
- Exclusive ShearWave™ technology,
- Use in both Neuro and General surgery.



### CUSA SaberTip™

- Designed for bone sculpting,
- 180° Abrasive surface to avoid surrounding damages,
- Removal of Meningioma with bone infiltration.



### MicroTip™ Plus

- Designed for transnasal skull base procedures,
- 19.27 cm long,
- 1.57 mm ID.



Procedures on Optic chiasm, Pituitary gland, hypothalamus, Sella turcica...

## 6.4. Tips technical data

### • Tip 36 kHz

HP	Tip	Product #	Diameter	Length	Weight	Amplitude	Surgical applications
36 kHz	PrecisionTip™ (short)	C4606S	1.14 mm	5.64 cm	68g	191-210 microns	Small, shallow, hard tumors
	PrecisionTip™ (extended)	C4607S	1.14 mm	12.5 cm	68g		Small, deeper, hard tumors
	PrecisionTip™ (extended curved)	C4608S	1.14 mm	12.5 cm	68g		Small, deeper, hard tumors
	MicroTip™ (short)	C4609S	1.57 mm	5.28 cm	68g	175-193 microns	Soft brain tumor
	MicroTip™ (extended)	C4610S	1.57 mm	12.15 cm	68g		Soft brain tumor
	MicroTip™ (extended curved)	C4611S	1.57 mm	12.15 cm	68g		Soft brain tumor
	Standard Tip (short)	C4612S	1.98 mm	4.57 cm	68g	137-155 microns	Soft brain tumor
	Standard Tip (extended)	C4613S	1.98 mm	11.44 cm	68g		Soft brain tumor
	Standard Tip (extended curved)	C4614S	1.98 mm	11.44 cm	68g		Soft brain tumor
	MicroTip™ Plus	C4615S	1.57 mm	19.27 cm	68g	137-155 microns	Soft brain tumor, Deeper applications
	SaberTip™	C4616S	1.14 mm (2.85 mm outer)	11.49 cm	68g	117-135 microns	Application where precise & controlled removal of bone is critical
	ShearTip™	C4617S	1.57 mm	11.79 cm	68g		Fibrous and tough tumors / Cirrhotic tumors

### • Tip 23 kHz

HP	Tip	Product #	Diameter	Length	Weight	Amplitude	Surgical applications
23 kHz	MicroTip™	C4600S	1.57 mm	9.22 cm	180g	Straight: 279-355 microns, Angled: 127-183 microns	Harder brain tumor
	Standard Tip (short)	C4601S	1.98 mm	7.98 cm	180g	Straight: 287-355 microns, Angled: 112-163 microns	Liver resection
	Standard Tip (extended)	C4602S	1.98 mm	18.38 cm	180g		Liver resection
	Standard Tip (extended curved)	C4603S	1.98 mm	18.38 cm	180g	287-355 microns (not compatible w/ angled handpiece)	Liver resection
	Laparoscopic	C4604ELT	1.98 mm (2.54 mm outer)	30.14 cm	180g	178-229 microns (not compatible w/ angled handpiece)	Acute Lap Chole; Hepatectomy; Endometriosis; Radical Prostatectomy; Pelvic Lymph Node Dissection
	MacroTip™	C4605S	2.64 mm	7.95 cm	180g	Straight: 254-307 microns, Angled: 102-142 microns	Liver resection

## 7. CUSA EXcel®+ exclusive features

### TissueSelect™ Technology

The TissueSelect™ feature enables surgeons to choose a setting that maintains a high rate of tissue fragmentation while maximizing selectivity and tactile feedback from the surgical site.

The total amount of power available is directly related to the amount of reserve power available to the vibrating tip. Reserve power is necessary to maintain tip vibration when in contact with tissue or under load. This is similar to cruise control in a car going up a hill; more power is provided to maintain the speed of the car. TissueSelect™ reduces the reserve power by pulsing the energy to the tip. This makes tissue destruction more controllable.

The TissueSelect™ feature provides increased selectivity both by creating periods of measured on/off intervals of power and by reducing the amount of reserve power. When the reserve power is significantly reduced, a wider margin of safety is provided when contacting high-strength tissue. As the setting is increased, « softer » tissue is still easily fragmented, but stronger tissue is more resistant, providing superior tactile feedback.

### TipSelect™ feature

TipSelect™ is a selective tissue removal system. This system allows for the selection of the most appropriate tip based on the consistency, location, depth and access of tumors. For added flexibility, tips can be changed in the sterile field, rather than the entire handpiece, optimizing the handpiece for the procedure.

### Cooling water system

The high frequency vibration generates heat. To reduce the heat, the CUSA EXcel®+ system includes a closed, recirculating cooling water system. This system pumps water from a cooling water reservoir, through a tube in the handpiece cable, through the handpiece, and through a return tube in the handpiece cable to the cooling water reservoir. Cooling water flows at 35 to 50 cc/min. As it passes through the handpiece, the water removes heat. Normal handpiece temperature, in sustained heavy use, remains at about 40° C.

### Built In Suction

A vacuum pump in the console body provides up to 660 mm mercury maximum vacuum at sea level. It means that users don't have to connect an additional pump making the set-up easier and faster.

Requirements	CUSA EXcel®+ answers	Comments
High selectivity mode	TissueSelect™ feature	Increase selectivity thanks to exclusive CUSA EXcel®+ system feature.
Changing tip during procedure	TipSelect™ feature	Possibility to change tip during procedure while keeping the same handpiece.
Electrosurgery	CEM™ Nonecone	The patented CEM™ nosecone combined with Forcefx™ generator adds electrosurgery to the CUSA EXcel®+ system. Forcefx is a product of ValleyLab, a division of Tyco healthcare group LP.
Bone removal	SaberTip™	Selective bone removal around critical structures thanks to the abrasive design of the tip.
Hard and fibrous tissue ablation	ShearTip™	Combine ultrasound selectivity and specific design for high efficiency on tough and fibrous tissue in both neuro and hepatic applications.
Transphenoidal approach	MicroTip™+	Improved access for transnasal and other procedures requiring extended length (11.49 cm) and small diameter for better visualization.
Laparoscopic surgery	Laparoscopic tip	A 30.14 cm long tip for laparoscopic approach in general surgery procedures. no need to specific handpiece.
Large range of tips	18 tips choice	Makes the CUSA EXcel®+ ultrasonic aspirator usable in a large range of applications and surgeons more confident when using it.

## 8. CUSA EXcel®+ requirements

Items required for each procedure: (Alternative configuration with non sterile tip and torque base is possible)

CUSA EXcel®+ console



Decontamination Guard



Handpiece (36 or 23kHz)



Torque base sterilizable



Disposable items required for each procedure:

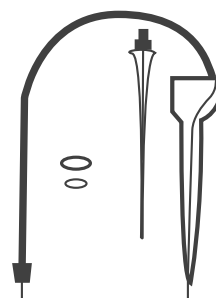
Torquing wrench



Tubing set



Tip set



Optional CEM™ Nosecone when ESU is required



## 9. CUSA EXcel®+ system

### PRODUCT INFORMATION

Model	Ultrasonic Aspirator CUSA EXcel®+ / CUSA EXcel® 9
Manufacturer details	Integra Lifesciences (Ireland) Limited - IDA Business and technology park - Sragh - Tullamore - County Offaly - IRELAND
1 <sup>st</sup> year on market	1998
Version	VERSION 3
Delivery delay	MINIMUM 1 WEEK
	MAXIMUM 1 MONTH

### REGULATORY COMPLIANCE (European Directive 93/42/EEC)

- CE certificates	CE12756
- class of device	IIB
- notified body	BSI Product Service, 0086

### PHYSICAL CHARACTERISTICS & ENVIRONMENT

Dimensions (L x l x h)	71.12 X 55.88 X 132CM
Weight (kg)	95.3 kgs
Electrical supply	
- voltage	220-240V
- power	110-120 VA
Liquids supply	Several fluids: Internal suction pump in conformity with standards
- water	Unmineralized water for cooling system
- vacuum	On board pump
Cooling system	The device is equipped with a closed water cooling system
Environment specificities	
- functioning temperature	10 to 40°C
- hygrometry	15 to 80% of humidity, without condensation

## DEVICE SPECIFICATIONS (1/2)

### GENERAL PRESENTATION

- device mobile	Yes
- number of wheels	4
- blocking system for wheels	Brakes on frontal wheels and blocking system on back wheels

### DEVICE CHARACTERISTICS

Technology used to produce ultrasounds and explanations	<p>The CUSA EXcel® console provides alternating current at 23 or 36 thousand cycles per second (kHz) to the handpiece (the frequency depends on which handpiece that are connected to the console). In the handpiece, the current passes through a coil, which induces a magnetic field. The magnetic field excites a transducer of nickel alloy laminations, resulting in an oscillating motion in the transducer laminated structure – vibration – along its long axis. The transducer vibrates at 23 or 36 kHz.</p>
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The transducer transmits vibrations through a metal connecting body to an attached surgical tip. The frequency of vibration remains the same at the tip (23 or 36 kHz), but the amount of motion (amplitude) at the tip varies: Lower frequency, greater amplitude; higher frequency, smaller amplitude.

### Fragmentation Mode

- Ultrasound power	100W
- Settings	Amplitude : 10 values, linear from 10 to 100%; default value is 10%
- Fonctioning Mode	The console provides alternating current at 23 or 36kHz to the handpiece and vibrations will be created by user when pushing on pedal.

### Irrigation Mode

- Flow rate (in ml/min) and precision	Flow rate is from 1 to 10cc/min, default setting is 3cc/minute
- Settings	10 values, linear from 1 to 10 CC/MIN
- Needed accessories	Tubing kit / Tip's flue

### Suction Mode

- Depression range (in hPa) and precision	Internal suction pump providing suction up to 660mm of mercury
- Settings	Touch screen to increase or decrease suction from 10 to 100%, by step of 10%
- Needed accessories	Tubing kit

## DEVICE SPECIFICATIONS (2/2)

Handpieces & tips: General characteristics:

- Raw material for ultrasound production parts	Nickel lamination and brass coil
- Raw material for the tip	Titanium
- Connection between handpiece and console	The handpiece is linked to the console by an electric cable and 2 silicon tubing for suction and irrigation.
- Cables lengths	4.60 m
- Protocol of decontamination	Handpiece and accessories should be cleaned with a brush then immersed in a decontamination liquid (the handpiece connector can not be immersed in a liquid without CUSA EXcel® caps).
- Protocol of sterilisation	Autoclave at 134°C during 18 min or what is in force in your country.
- Max. number of use (handpiece)	150
- Tip's choice	Single use or Reusable tips. Assembly with sterile or non-sterile torquing set according to user's choice.
- Setting time	About 2 min for assembly
- Dismantling steps for cleaning	Use of Torquing set
- Tools to connect and disconnect tips from handpieces	Torquing set composed by Torque base and wrench
Handpiece (to fill in for each model):	36 kHz straight Handpiece
- Type of surgery	Mainly neurosurgery but wide range of applications (see user manual)
- Accessories (tips etc.)	Tips, tubing, torque set, sterilization case, maintenance kit (depending of the offer).
- Weight	68g
- Handpiece length	13.9 cm
- Ultrasounds frequency (in Hz)	36000Hz
- Maximum Vibration amplitude (in µm)	From 137 to 210 microns (Depending of tip / handpiece combination and setting)
Handpiece (to fill in for each model):	23 kHz straight Handpiece
- Type of surgery	Mainly general and hepatic surgery but wide range of applications (see user manual).
- Accessories (tips etc.)	Tips, tubing, torque set, sterilization case, maintenance kit (depending of the offer).
- Weight	140g
- Handpiece length	22.2cm
- Ultrasounds frequency (in Hz)	23 000 Hz
- Maximum Vibration amplitude (in µm)	From 178 to 355 microns: Depending of tip / handpiece combination and setting.



## 10. CUSA EXcel®+ documents

The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.

Certificate	
<b>Full Quality Assurance</b>	
<b>No. CE 512756</b>	
Issued to:	
<b>Integra LifeSciences (Ireland) Ltd IDA Business &amp; Technology Park Sragh Tullamore Offaly Ireland</b>	
In respect of:	
<b>Design and Manufacture of Ultrasonic Surgical Aspirators and associated sterile and non-sterile accessories</b>	
on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.	
For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):	
	
David Ford, Director, Healthcare and Testing Services	
First Issued: 5 Apr 2007	Date: 27 May 2010
Expiration Date: 4 Apr 2012	Page: 1 of 1
<i>Conditions of Approval</i> Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.	
raising standards worldwide™	
	
<small>The British Standards Institution, trading as BSI, a company incorporated in the United Kingdom by Royal Charter and with its place of business at 389 Chiswick House, Uxbridge Avenue, Uxbridge, Middlesex UB2 4JQ, United Kingdom. Tel: +44 (0)345 755600. Web: www.bsi-group.com. BSI Group Headquarters: 389 Chiswick House, Uxbridge, London W4 4AL. Tel: +44 (0)20 8996 9000. P002756000000</small>	

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## Certificate

### Design Examination

**No. CE 559055**

Issued to:

**Integra LifeSciences (Ireland) Ltd**  
**IDA Business & Technology Park**  
**Sragh**  
**Tullamore**  
**Offaly**  
**Ireland**

In respect of:

**Tips and Flues for CUSA EXcel Ultrasonic Surgical Aspirator System**

On the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 4,  
 For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):



David W. Ford, Executive Director, Healthcare and Testing

First Issued: 11 Jun 2010

Date: 11 Jun 2010

Expiration Date: 10 Jun 2015

Page: 1 of 4



*Conditions of Approval*  
 Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

*raising standards worldwide™*



The British Standards Institution, trading as BSI, a company incorporated in the United Kingdom by Royal Charter and with its office of business at Kitemark House, Marylands Avenue, Hemel Hempstead HP2 4SQ United Kingdom. Tel: +44 (0)8450 765000. Web: www.bsigroup.com. BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL, Tel: +44 (0)20 8996 9000. 111022-0000-00

The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.



## EC Declaration of Conformity

By

### Integra LifeSciences (Ireland) Limited

Declare under our sole responsibility, that our Product Group Equipment covered by this declaration:

**CUSA EXcel® (CUSA EXcel® & CUSA EXcel®8) and CUSA EXcel®+ (CUSAEXcel®9) family of Ultrasonic Surgical Aspirator Systems**

Conforming to Directive 93/42/EEC, Annex II per Article 11, this declaration is supported by compliance with the Essential Requirements by meeting the following Standards:

EN55011, EN(IEC) 60601-1, EN (IEC) 60601-1-2, EN (IEC) 60601-2-2, UL2601-1, ISO 13485: 2003

Product Group	93/42/EEC Annex IX Rule	93/42/EEC Annex IX Class
<b>TF03-01*</b> CUSA EXcel®, CUSA EXcel®8 and CUSA EXcel®9 Console	<b>9</b>	<b>IIb</b>
<b>TF03-02*</b> CUSA EXcel® Handpieces	<b>9</b>	<b>IIb</b>
<b>TF03-04*</b> CUSA EXcel® Sterile Manifold Tubing	<b>2</b>	<b>IIa Sterile</b>

Reference the table in the following page for list product codes covered under this declaration

Signed by:

  
Tony O'Hanlon  
QA/RA Manager

Date: April 14, 2010

EC Certificate Number: **CE 512756**

Notified Body: **BSI Product Certification (0086)**

Nominated holder of documents:

Integra LifeSciences (Ireland) Limited  
IDA Business & Technology Park  
Sragh  
Tullamore  
Co. Offaly  
Ireland

TF03\_A02\_CUSA\_Accessories\_DoC\_Class IIa\_IIb\_1.2, CRN 10/0713

Page 1 of 2

The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.



## EC Declaration of Conformity By Integra LifeSciences (Ireland) Limited

### List of Articles/Reference Numbers

REF	PRODUCT
CUSAEXCEL	EXcel Console with Footswitch
CUSAEXCEL8	EXcel-8 Console with Footswitch
CUSAEXCEL9	EXcel9 Console with footswitch
150000090	EXcel Footswitch
C2600	EXcel 23kHz Straight Hand piece
C2601	EXcel 23kHz Angled Hand piece
C2602	EXcel 36kHz Straight Hand piece
C6623	EXcel 23kHz CEM Nosecone
C6636	EXcel 36kHz CEM Nosecone
C3600	EXcel 23kHz Tubing Set
C3601	EXcel 36kHz Tubing Set

The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.



## EC Declaration of Conformity

By

### Integra LifeSciences (Ireland) Limited

Declare under our sole responsibility, that our Product covered by this declaration for Belarus:

**Tips and Flues for the CUSA EXcel<sup>®</sup> family of Ultrasonic Surgical Aspirator Systems**

Conforming to Directive 93/42/EEC, Annex II.3 and Annex II.4 per Article 11, this declaration is supported by compliance with the Essential Requirements by meeting the following Standards:

ISO 13485: 2003

Product Group	93/42/EEC Annex IX Rule	93/42/EEC Annex IX Class
DDIRL-001 CUSA EXcel <sup>®</sup> Tips and Flues	Rule 6, Indent 3	III

Reference the tables in the following page for list product codes covered under this declaration

Signed by:

  
Tony O'Hanlon  
QA/RA Manager

Date:

June 23rd 2010

EC Certificate Number: CE559055

Notified Body: BSI Product Certification (0086)

Nominated holder of documents:

Integra LifeSciences (Ireland) Limited  
IDA Business & Technology Park  
Sragh  
Tullamore  
Co. Offaly  
Ireland

DDIRL\_001\_CUSA TIP & Flue\_DoC\_Class\_III\_1.0 Belarus, CRN 10/0746

Page 1 of 2

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## Tips and Flues for CUSA EXcel Ultrasonic Surgical Aspirator System

Sterile Tip and Flue Sets for single use*	
Product Code	Product Description
C4600S	EXcel 23kHz MicroTip™ and Flue
C4601S	EXcel 23kHz Standard Tip and Flue
C4602S	EXcel 23kHz Straight Extended Standard Tip and Flue
C4603S	EXcel 23kHz Curved Extended Standard Tip and Flue
C4605S	EXcel 23kHz MacroTip™ and Flue
C4606S	EXcel 36kHz PrecisionTip™ and Flue
C4607S	EXcel 36kHz Straight Extended PrecisionTip™ and Flue
C4608S	EXcel 36kHz Curved Extended PrecisionTip™ and Flue
C4609S	EXcel 36kHz MicroTip™ and Flue
C4610S	EXcel 36kHz Straight Extended MicroTip™ and Flue
C4611S	EXcel 36kHz Curved Extended MicroTip™ and Flue
C4612S	EXcel 36kHz Standard Tip and Flue
C4613S	EXcel 36kHz Straight Extended Standard Tip and Flue
C4614S	EXcel 36kHz Curved Extended Standard Tip and Flue
C4615S	EXcel 36kHz MicroTip™ Plus and Flue
C4616S	EXcel 36kHz SaberTip™ and Flue
C4617S	EXcel 36kHz ShearTip™ and Flue
C4617SEA	EXcel 36kHz ShearTip™ and Flue

\* Sets comprises of 1 Tip, 1 Flue, large O-ring, small O-ring and a Tip cleaning wire

Non sterile Reusable Tip in set with 6 Flues*	
Product Code	Product Description
C4601ELT	EXcel 23kHz Standard Tip Extended Life and Flues
C4604ELT	EXcel 23kHz Laparoscopic Tip Extended Life and Flues
C4605ELT	EXcel 23kHz MacroTip™ Extended Life and Flues
C4608ELT	EXcel 36kHz Curved Extended PrecisionTip™ Extended Life and Flues
C4611ELT	EXcel 36kHz Curved Extended MicroTip™ Extended Life and Flues
C4614ELT	EXcel 36kHz Curved Extended Standard Tip Extended Life and Flues

\* Non sterile Sets comprises of 1 reusable Tip (up to 6 times reusable), 6 Flues, 6 large O-rings, 6 small O-rings and 6 Tip cleaning wires

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TF03

## EC Declaration of Conformity

By

### Integra LifeSciences (Ireland) Limited

Equipment covered by this declaration:  
ACCESSORIES FOR CUSA EXcel® (CUSA EXcel®) & CUSA EXcel®+ (CUSA EXcel®9) SYSTEMS

Product Group	93/42/EEC Annex IX Rule	93/42/EEC Annex IX Class
TF03-05* Steriliser Case, Tip Torquing Set, Contamination Guard, Tip Maintenance Kit, Sterilizable Torque Base, Specimen Trap	I	I
TF03-06* Sterile Disposable Wrench Set	I	I Sterile
TF03-07* Re-useable Nosecones	I	I

\* REFs listed in Appendix I

We declare under our sole responsibility that the listed product groups are Conforming to Directive 93/42/ECC, Annex VII, plus Annex V (Sterile), this declaration is supported by compliance with the Essential Requirements and by meeting the following Standard(s):

ISO 13485: 2003

Signed by:

  
Tony O'Hanlon  
QA/RA Manager

Date:

April 14, 2010

EC Certificate Number, Annex V: CE 517843 (Sterile)

Notified Body: BSI Product Services, 0086

Nominated holder of documents:-

Integra LifeSciences (Ireland) Limited  
IDA Business and Technology Park  
Sragh  
Tullamore  
County Offaly  
Ireland

TF03\_A02-02\_CUSA\_Accessories\_DoC\_Class\_1\_v1.2, CRN 10/0713

Page 1 of 2



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TF03

## EC Declaration of Conformity

By

### Integra LifeSciences (Ireland) Limited

#### Appendix 1

#### List of Articles/Reference Numbers

REF	PRODUCT
C0005	EXcel Contamination Guard
C0023	EXcel 23kHz Handpiece ELT Maintenance Kit
C2623	EXcel 23kHz Sterilization Case
C2636	EXcel 36kHz Sterilization Case
C5600	EXcel Tip Torquing Set
C5601	EXcel 23kHz Disposable Wrench
C5602	EXcel 36kHz Disposable Wrench
C5623	EXcel 23kHz Sterilizable Torque Base
C5636	EXcel 36kHz Sterilizable Torque Base
CV260438000	EXcel Specimen Trap
C380761000	EXcel 23kHz Re-Usable Nosecone, finished device
C223600215	EXcel 36kHz Re-Usable Nosecone, finished device



The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.

Certificate	
<b>Production Quality Assurance</b>	
<b>No. CE 517843</b>	
Issued to: <b>Integra LifeSciences (Ireland) Ltd</b> <b>IDA Business &amp; Technology Park</b> <b>Sragh</b> <b>Tullamore</b> <b>Offaly</b> <b>Ireland</b>	
In respect of: <b>Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of sterile disposable Excel wrench sets</b>	
on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2. For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):	
	
David Ford, Director, Healthcare and Testing Services	
First Issued: 5 Apr 2007	Date: 25 May 2010
Expiration Date: 4 Apr 2012	Page: 1 of 1
<b>Conditions of Approval</b> Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.	
<i>raising standards worldwide™</i>	
	
<small>The British Standards Institution, trading as BSI, a company incorporated in the United Kingdom by Royal Charter and with its place of business at Kitemark House, 150/151, Market Avenue, Hemel Hempstead HP2 4SQ, United Kingdom. Tel: +44 (0)8452 750600. Web: www.bsigroup.com. BSI Group Headquarters: 389 Chiswick High Road, London W4 4AL, Tel: +44 (0)20 8996 9000. P1702X000000</small>	

The following documents are valid at the date when this document was printed. One should regularly check with Integra if an updated version was issued.



# Certificate of Registration

**QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003**

*This is to certify that:*

**Integra LifeSciences (Ireland) Ltd**  
**IDA Business & Technology Park**  
**Sragh**  
**Tullamore**  
**Offaly**  
**Ireland**

*Holds Certificate No: FM 512757*  
*and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:*

**The design and manufacture of ultrasonic surgical aspirator systems, with associated adaptors, hand pieces, tips, flues, tubing and system accessories.**

*For and on behalf of BSI:*

  
 \_\_\_\_\_  
 President, BSI America, Inc.

Originally Registered: 03/22/2007

Effective Date: 03/22/2010

Expiry Date: 03/21/2013



**CMDCAS  
Recognized  
Registrar**

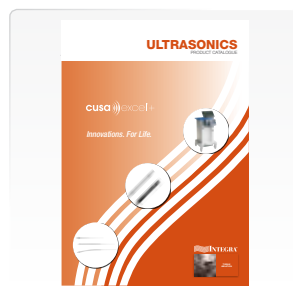


Page: 1 of 1

This certificate remains the property of BSI and shall be returned immediately upon request.  
 An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory).  
 To be read in conjunction with the scope above or the attached appendix.  
 Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.



## Available CUSA EXcel®+ documents



### CUSA EXcel®+ catalogue

English

[ILS 04-02-002-03-09](#)

French

[ILS 04-02-016-01-09](#)

German

[ILS 04-02-003-03-10](#)



### CUSA EXcel® techbrief

English

[ILS 04-105-01-07](#)

French

[ILS 04-109-01-07](#)

German

[ILS 04-110-01-07](#)



### CUSA EXcel® salesheet

English

[ILS 04-113-01-08](#)

French

[ILS 04-01-020-01-08](#)

German

[ILS 04-01-021-01-08](#)



### CUSA EXcel® sabertip™ salesheet

English

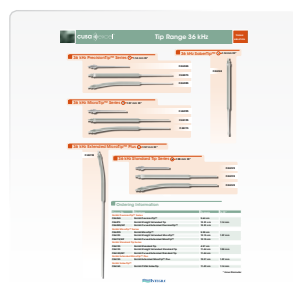
[ILS 04-103-01-07](#)

French

[ILS 04-107-01-07](#)

German

[ILS 04-104-01-07](#)



### CUSA EXcel® wallchart

English

[ILS 04-04-005-01-08](#)

French

[ILS 04-04-007-01-08](#)

German

[ILS 04-04-008-01-08](#)



### CUSA ShearTip™ salesheet

English

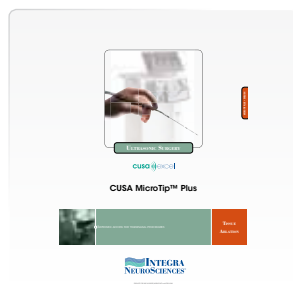
[ILS 04-01-035-01-10](#)

French

[ILS 04-01-036-01-10](#)

German

[ILS 04-01-037-01-10](#)



### CUSA MicroTip™ plus salesheet

English

[ILS 04-01-004-01-07](#)

French

[ILS 04-01-010-01-07](#)

German

[ILS 04-104-01-07](#)



### DVD in-service dvd CUSA EXcel®

English

[ILS 04-302-01-07](#)

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